

Application No.: 10/643,315
Applicant(s): Spiridigliozzi, et al.
Docket No.: 760-100 CIP/RCE
Amendment and Response dated February 22, 2007

Listing of Claims

This listing of claims will replace all prior versions and listings of claims in the subject application:

1. (Currently Amended) A composite multilayer implantable material comprising:

a first inner tubular layer formed of expanded polytetrafluoroethylene having a porous microstructure defined by nodes interconnected by fibrils, wherein said first layer has a plurality of pleated folds;

a second tubular layer formed of textile material circumferentially disposed exteriorly to said first layer; and having

an elastomeric bonding agent applied to one of said first layer or second layer for securing portions of said first layer located between said pleated folds to said second layer, said pleated folds not being secured to said second layer, wherein said second layer is disposed over said secured portions and said pleated folds.
2. (Original) The implantable material of claim 1 wherein said bonding agent is applied to one surface of said first layer.
3. (Original) The implantable material of claim 1 wherein said bonding agent is selected from the group consisting of urethanes, styrene/isobutylene/styrene block copolymers, silicones and combinations thereof.

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4. (Original) The implantable material of claim 1 wherein said second layer comprises a textile pattern selected from the group comprising knits, weaves, stretch-knits, braids, any non-woven process, and combinations thereof.
5. (Original) The implantable material of claim 1 wherein said second layer is placed in contact with said one surface of said first layer.
6. (Original) The implantable material of claim 1 wherein said implantable material includes said first layer being a blood contact layer and said second layer being a tissue contacting layer.
7. (Original) The implantable material of claim 1 wherein said first, and second tubular layers form an elongate tubular vascular graft.
8. (Original) The implantable material of claim 7 wherein said graft includes a plurality of longitudinally spaced crimps therealong.
9. (Original) The implantable material of claim 7 wherein said graft is helically wrapped with a monofilament externally therearound.

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10. (Original) The implantable material of claim 9 wherein said monofilament comprises polypropylene.
11. (Original) The implantable material of claim 10 wherein said monofilament is attached by heat bonding.
12. (Original) The implantable material of claim 9 wherein said graft includes an external support coil helically positioned thereover.
13. (Original) The implantable material of claim 1 wherein said elastomeric bonding agent is applied to said second layer in solution.
14. (Original) The implantable material of claim 13 wherein said solution includes dimethylacetamide.
15. (Original) The implantable material of claim 1, wherein the pleats are of uniform length.
16. (Withdrawn) The implantable material of claim 1, wherein the pleats are of variable length.
17. (Original) The implantable material of claim 1, wherein the pleats have uniform spacing.

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18. (Withdrawn) The implantable material of claim 1, wherein the pleats have variable spacing.

19. (Currently Amended) A composite multilayer implantable structure comprising:

a first inner tubular layer formed of expanded polytetrafluoroethylene having a porous microstructure defined by nodes interconnected by fibrils, and a second tubular layer of expanded polytetrafluoroethylene circumferentially disposed exteriorly to said first layer, wherein said first and second layers have a plurality of pleated folds, each of said pleated folds being provided by doubling a continuous portion of said first layer and said second layer upon itself and pressing said continuous portion into an adjacent portion, and wherein said first and second layers having a support structure positioned therebetween,

a third tubular layer formed of textile material circumferentially disposed exteriorly to said second layer; and

an elastomeric bonding agent applied to one of said second layer or third layer for securing said second layer to said third layer.

20. (Original) A composite structure of claim 19 wherein said bonding agent is applied to one surface of said first layer.

21. (Currently Amended) A composite structure of claim 19 wherein said bonding agent is applied to a surface of said ~~second~~ third textile layer.

22 (Original) A composite structure of claim 19 wherein said bonding agent is selected from the group consisting of urethanes, styrene/isobutylene/styrene block copolymers, silicones and combinations thereof.

23. (Original) A composite structure of claim 19 wherein said third layer comprises a textile pattern selected from the group comprising knits, weaves, stretch-knits, braids, any non-woven process, and combinations thereof.

24. (Original) A composite structure of claim 19 wherein said third layer is placed in contact with said one surface of said second layer.

25. (Original) A composite structure of claim 19 wherein said implantable structure includes said first layer being a blood contact layer and said third layer being a tissue contacting layer.

26. (Original) A composite structure of claim 19 wherein said first, second and third tubular layers form an elongate tubular vascular graft.

27. (Original) A composite structure of claim 26 wherein said graft includes a plurality of longitudinally spaced crimps therealong.

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28. (Original) A composite structure of claim 26 wherein said graft is helically wrapped with a monofilament externally therearound.
29. (Original) A composite structure of claim 26 wherein said monofilament comprises polypropylene.
30. (Original) A composite structure of claim 29 wherein said monofilament is attached by heat bonding.
31. (Original) A composite structure of claim 28 wherein said graft includes an external support coil helically positioned thereover.
32. (Original) A composite structure of claim 19 wherein said elastomeric bonding agent is applied to said second layer in solution.
33. (Original) A composite structure of claim 32 wherein said solution includes dimethylacetamide.
34. (Withdrawn) A composite structure of claim 19 further comprising a fourth tubular layer formed of textile material circumferentially disposed interiorly to said first and second layers; and

an elastomeric bonding agent applied to one of said first layer or said fourth layer for securing said first layer to said fourth layer.

35. (Original) The implantable material of claim 19, wherein the pleated folds are of uniform length.

36. (Withdrawn) The implantable material of claim 19, wherein the pleated folds are of variable length.

37. (Original) The implantable material of claim 19, wherein the pleated folds have uniform spacing.

38. (Withdrawn) The implantable material of claim 19, wherein the pleated folds have variable spacing.

39. (Withdrawn) A method of forming a textile ePTFE composite graft material comprising:
providing a first tubular ePTFE structure having a microporous structure of nodes interconnected by fibrils;
providing a second tubular ePTFE structure having a microporous structure of nodes interconnected by fibrils;

folding a plurality of pleats into said first tubular ePTFE structure and said second tubular ePTFE structure;

providing a tubular textile structure;

placing a tubular support structure circumferentially around said first ePTFE tubular structure;

placing said second tubular ePTFE structure circumferentially around said tubular support structure;

applying a coating of an elastomeric bonding agent to a surface of said second ePTFE structure or said textile structure; and

securing said second ePTFE structure to said textile structure.

40. (Withdrawn) A method of claim 39 wherein said tubular textile structure defines an inner and outer surface.

41. (Withdrawn) A method of claim 40 wherein said first and second ePTFE tubular structures are applied to said inner surface of said textile structure.

42. (Withdrawn) A method of claim 39 wherein said bonding agent is applied to one surface of said second ePTFE structure.

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43. (Withdrawn) A method of claim 42 wherein said bonding agent is selected from the group consisting of urethanes, styrene/isobutylene/styrene block copolymers, silicones, and combinations thereof.
44. (Withdrawn) A method of claim 39 wherein said textile structure is formed by a process selected from the group consisting of knitting, weaving, stretch-knitting, braiding, any non-woven process, and combinations thereof.
45. (Withdrawn) A method of claim 39 wherein said elastomeric bonding agent is applied to said one surface in solution.
46. (Withdrawn) A method of claim 45 wherein said solution includes dimethylacetamide.
47. (Withdrawn) A method of claim 39 further comprising the following steps:
- applying an elastomeric bonding agent to an interior surface of said first ePTFE tubular structure;
 - placing a fourth tubular structure formed of textile material circumferentially interior to said first and second ePTFE tubular layers; and
 - bonding said layers together.